PTO/SB/08A (08-00)

Approved for use through 10/31/2002 OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE to a collection of information unless it contains a valid OMB control number

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERC under the Pagerwork Reduction Agost 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control numb

Substitute for Form 1449/A/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary of 5

Cor	nplete if Known
Application Number	10/534,773
Filing Date	May 13, 2005
First Named Inventor	Robertson
Group Art Unit	1643
Examiner Name	Lynn Anne Bristol
Attorney Docket Number	49409-0050 (315804)

					U.S. PATENT DOCUMENT	S	
Exam Initia		Cite No. ¹	U.S. Patent Docur	nent Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
48	8	1	US-4,898,951		Symons	02-06-1990	
		2	US-4,937,185		Webb et al.	06-26-1990	
		3	US-5,157,020		Kay et al.	10-20-1992	
		4	US-5,652,115		Marks et al.	07-26-1990	
		5	US-5,726,023		Cheever et al.	03-10-1998	
	,	6	US-5,876,728		Kass et al.	03-02-1999	•
		7	US-6,322,989		Cohen	11-27-2001	
	/	8	US 2002016869	6	Hanash	11-14-2002	

						FOF	REIGN PATENT DOCUMEN	NTS		
Exan		Cite No.1		Offi	Foreign Patent Doc ce ³ Number ⁴	Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	To
74	S	9	•		EP 0 236 606	5	Imre Corporation	06-24-1992		
		10	\dashv		JP 09 189702		Hitachi Chem Co. Ltd.	07-22 1997		\vdash
14	aR .	11	•		WO 92/1306	5	Novo Nordisk A/S	08-06-1992		
		12	٠		WO 93/1123	6	Medical Research Council	06-10-1993		
		13	1		WO 93/2152	9	Marks et al.	10-1993 .	1	
		14	•		WO 94/2372	8	Northwestern University	10-27-1994	,	
		15	•		WO 96/0008	4	Torchilin et al.	01-04-1996	`	
		16	 •		WO 96/0350	2 A2	Ramot University Authority for Applied Research and Industrial Development Ltd.	02-08-1996		
		17	•		WO 97/1479	4	Lane et al.	04-24-1997		
	/	18	•		WO 00/2666	58	The Regents of the University of Michigan	05-11-2000		

	n Diatali			03/27/2007
Examiner	/Lynn Bristol/	o	Date	03/21/2001
Signature			Considered	

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002 OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

			Con	nplete if Known
Substitute f	or Form 1449/A/PTO		Application Number	10/534,773
	NEODMATIC	N DICCI OCUBE	Filing Date	May 13, 2005
	· · · · · · · · · · · · · · · · · · ·	N DISCLOSURE	First Named Inventor	Robertson
,	STATEMENT	BY APPLICANT	Group Art Unit	1643
	(use as many	sheets as necessary	Examiner Name	Lynn Anne Bristol
Sheet	2	15	Attorney Docket Number	49409-0050 (315804)

			OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS	
	miner tials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
		19°	APARECIDA et al., "Value of CEA Level Determination in Gallbladder Bile in the	
4	$ \mathcal{S}_{\mathbf{k}} $		Diagnosis of Liver Metastases Secondary to Colorectal Adenocarcinoma", Sao Paulo	
			Medical Journal, 2001, Volume 119, No. 3, pp. 110-113.	
		204	APOSTOLOPOULOS et al., Nature Medicine, 1998, Vol. 4, pp. 315-320.	
		21 °	BAECHSTROM, et al., "Purification and Characterization of Sialyl-Le - Carrying Mucins	
i			of Human Bile; Evidence for the Presence of MUC1 and MUC3 Apoproteins", The Journal	
			of Biological Chemistry, 1994, Volume 269, No. 20, pp. 14430-14437.	
		22 •	BEATTY, et al., "Biochemical Characterization of the Soluble Form of Tumor Antigen	
			MUC1 Isolated from Sera and Ascites Fluid of Breast and Pancreatic Cancer Patients",	
			Clinical Cancer Research, 2001, Vol. 7, pp. 781-787.	<u></u>
			BEN-MAHREZ et al., British Journal of Cancer, 1988.	
		24 •	BHATTI et al.; Journal of Tumor Marker Oncology, Summer-1994, Vol. 9, pp. 125-131.	ļ
			CROCE et al.; Cancer. Immunol. Immunother., 1995, Vol. 40, pp. 132-137.	
			DEGUCHI et al.; Int. Arch. Allergy Appl. Immunol., 1988, Vol. 87, pp. 313-316.	<u> </u>
			DENTON et al.; Cancer Letters, 1993, Vol. 70, pp. 143-150.	
		28 8	DISIS et al.; Journal of Clinical Oncology, 1997, Vol. 15, pp. 3363-3367.	
		29•	FISHMAN, P., "Application of autoantibodies to cancer therapy: A new concept", The 9th	
			International Congress of Immunology, 1995, p. 664.	
		30 *		
			immune complexes in carcinoma patients"; British Journal of Cancer; 72, pp. 934-938;	
			(1995).	ļ
			GREEN et al.; European Journal of Cancer, 1994, Vol. 30A, pp. 580-584.	
		32 °		
			a Novel cDNA Derived from the Tumor Suppressor Gene Locus on Chromosome 3p21.3",	
	_	00-	Ludwig Institute for Cancer Research, pp. 1034-1040	<u> </u>
	 		Abstract of HAYES; Anticancer Drugs, 1995, Vol. 6, suppl. 2, pp. 26-27.	<u> </u>
<u> </u>			HEHIR et al., Journal of Surgical Oncology, 1993, Vol. 54, pp. 207-210.	
		35*		
			Serous Cystadenocarcinoma of the Ovary", Molecular Immunology, 1981, Vol. 18, No. 7,	
	-	00.5	pp. 647-653.	
		36	HINODA, et al., "Detection of a Circulating Antibody Against a Peptide Epitope on a Mucin	
<i>y</i> _			Core Protein, MUC1, in Ulcerative Colitis", 1991, pp. 163-168.	

	•		03/27/2007
Examiner	/Lynn Bristol/	Date	03/21/2001
	/Lynn Bristol/	Date	•
Signature	\ _ ,	Considered	

¹Unique citation designation number. ²Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08A (08-00)
Approved for use through 10/31/2002 OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

				Cor	nplete if Known
Substitute t	for Form 1449/A/PTO			Application Number	10/534,773
	NIEODIA A	-101	A DICCLOCUDE	Filing Date	May 13, 2005
· ·			N DISCLOSURE	First Named Inventor	Robertson
	STATEME	NT	BY APPLICANT	Group Art Unit	1643
	(use as i	nany si	heets as necessary	Examiner Name	Lynn Anne Bristol
Sheet	3	of	5	Attorney Docket Number	49409-0050 (315804)

ſ .		OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²						
0	37 HOUGHTON et al.; "Detection of Cell Surface and Intracellular Antigens by Hum								
LAB		Monoclonal Antibodies - Hybrid Cell Lines Derived from Lymphocytes of Patients with							
		Malignant Melanoma"; J. Exp. Med.; Vol. 158, July 1983; pp. 53-65.							
	38 *	JANEWAY et al., Immunobiology, 5 th ed.							
	39 •	KARANIKAS, et al. J Clin Invest 1997 December 1, Vol. 100, No. 11, pp. 2783-2792.							
		KAWAHARA; Cancer, 1986, Vol. 58, pp. 2008-2012.							
		KOTERA et al.; Cancer Research, 1994, Vol. 54, pp. 2856-2860.							
	422	KURALAY, et al., "Diagnostic Usefulness of Tumour Marker Levels in Pleural Effusions of							
		Malignant and Benign Origin, Clinica Chimica Acta, 2000, Vol. 300, pp. 43-55.							
	43*	KUTTEH, W.H., et al., "Immunologic characterization of tumor markers in human ovarian							
		cancer cell lines"; Journal of the Society for Gynecologic Investigation, 1996, vol. 3, no. 4,							
		pp. 216-222.							
	44 •	LAENG, et al., "Anti-Neural Autoantibodies, types 1 and 2: Their Utility in the Study of							
		Tumors of the Nervous System", Acta Neuropathol, 1998, Vol. 96, pp. 329-339.							
	45 •	LAFOND, R.E., et al., "Autoantibodies to c-myc protein: elevated levels in patients with							
		African Burkitt's lymphoma and normal Ghanians", Autoimmunity, vol. 13, no. 3, 1992, pp.							
	İ	215-224.	L						
	46¢	LAI, et al., "Presence of Serum Anti-P53 Antibodies is Associated with Pleural Effusions							
		and Poor Prognosis in Lung Cancer Patients", Clinical Cancer Research, 1998, Vol. 4, pp.	1						
		3025-3030.							
	47 •	LAWNICZAK, et al., "The Search for Tumor-Associated Proteins in Pleural Effusions by							
		Means of Monoclonal Antibodies and a Dot Blot Assay", Lung, 1992, Vol. 170, pp. 65-74.							
	48 4	MERCER, "Use of Multiple Markers to Enhance Clinical Utility", Immunology Series, Vol.							
		53, 1990, pp. 39-54.							
	49 •	MONTENARH, et al., "P53 Autoantibodies in the Sera, Cyst and Ascitic Fluids of Patients							
		with Ovarian Cancer", International Journal of Oncology, 1998, Vol. 13, pp. 605-610.	ļ						
	50 •								
		Containing Carcinoembryonic Antigen-Like Activity", Br J. Cancer, 1974, Vol. 29, No. 413,							
	51 *	NUSTAD et al., "Epitopes on CA 125 from Cervical Mucus and Ascites Fluid and							
		Characterization of Six New Antibodies", pp. 303-314.							
1	52 •	Abstract of PANDHA et al.; Cancer Gene Therapy, 1997, Vol. 4, No. 5, page 310.	<u> </u>						

-	Evernings	/Lynn Bristol/	Date:	03/27/2007
]	Examiner	regrin briston	Date	
	Signature		Considered	

¹Unique citation designation number. ²Applicant is to place a check mark here if English language translation is attached.

				Complete if Known		
Substitute t	bstitute for Form 1449/A/PTO		Application Number	10/534,773		
	NICODIAAT	101	I DISCLOSUBE	Filing Date	May 13, 2005	
			N DISCLOSURE	First Named Inventor	Robertson	
	STATEMEN	1T	BY APPLICANT	Group Art Unit	1643	
	(use as m	any si	neets as necessary	Examiner Name	Lynn Anne Bristol	
Sheet	4	of	5	Attorney Docket Number	49409-0050 (315804)	

		OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²		
LAB	53	PAVELIC et al., Anticancer Reasearch, 1991, Vol. 11, pp. 1421-1428.			
	54 •	PETRARCA, C., "Human Antibodies Against the Polymorphic Epithelial Mucin in Ovarian Cancer Patients Recognise a Novel Sequence in the Tandem Repeat Region"; European Journal of Cancer, Vol. 32A, No. 12, pp. 2155-2163, 1996.			
	55 4	PETRAKOU et al.; International Journal of oncology, 1997, Vol. 11, suppl. Page 902.			
	56 2	RAO, S.G., "Detection of Human Ovarian Tumor Associated Antigens by Autologous Antibodies Isolated from Ovarian Carcinoma Ascites Fluid"; Proceedings of the American Association for Cancer Research Annual Meeting, 1987, vol. 28, p. 358.			
	57∙	RUSCIANO, "Concomitant Purification of Prostatic Carcinoma Tumor Markers from Human Seminal Fluid Under Nondenaturing Conditions", Clinical Chemistry, 1988, Vol. 34, No. 12, pp. 2528-2532.			
	58 •	SAHIN et al.; PNAS, 1995, Vol. 92, pp. 11810-11813			
	59 %	SANDRIN et al., Glycoconjugate Journal, 1997, Vol. 14, pp. 97-105.			
	60 °	SCANLAN et al.; International Journal of Cancer, 1998, Vol. 76, pp. 652-658			
	61 ₹	SCHNEIDER, J. "P53 Protein, EGF Receptor, and Anti-P53 Antibodies in Serum from Patients with Occupationally Derived Lung Cancer", British Journal of Cancer, 1999, Vol. 80, No. 12, pp. 1987-1994.			
	62•	SHIBATA, et al., "Purification and Characterization of Prostate Specific Antigen from Human Urine", Biochimica et Biophysica Acta, 1997, Vol. 1336, pp. 425-433.			
	63*	SOKOLOFF, et al., "A Dual-Monoclonal Sandwich Assay for Prostate-Specific Membrane Antigen: Levels in Tissues, Seminal Fluid and Urine", The Prostate, 2000, Vol. 43, pp. 150-157.			
	64 •	Abstract of STEARNS et al.; Breast Cancer Research and Treatment, 8 Feb. 1998, Vol. 52, pp. 239-259			
	65•	STUBBS, et al., "Faecal Carcinoembryonic Antigen (CEA) in Patients with Large Bowel Cancer", European Journal of Surgical Oncology, 1987, Vol. 13, pp. 433-436.			
	66∢	TONDINI, et al., "Comparison of CA15-3 and Carcinoembryonic Antigen in Monitoring the Clinical Course of Patients with Metastatic Breast Cancer", Cancer Research, 1988, Vol. 48, No. 14, pp. 4107-4112.			
4	67•	TOTH, et al., "A Carcinoembryonic Antigen (CEA) Binding Protein From Ascites Influences CEA Uptake by Macrophages", 1990, Vol. 171, No. 2, pp. 633-640.			

		·	
			00/07/0007
Examiner	/Lunio Deletal/	Date	03/27/2007
Signature	/Lynn Bristol/	Considered	

¹Unique citation designation number. ²Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002 OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE and to a collection of information unless it contains a valid OMB control number

Under the Paperwork Reduction Act of 1985, no persons are required to to decident of this master amount of this come control number				
Substitute for Form 1449/A/PTO		Complete if Known		
		Application Number	10/534,773	
	NEODMATION DICCLOSURE	Filing Date	May 13, 2005	
	INFORMATION DISCLOSURE	First Named Inventor	Robertson	
STATEMENT BY APPLICANT (use as many sheets as necessary		Group Art Unit	1643	
		Examiner Name	Lynn Anne Bristol	
Sheet	5 of 5	Attorney Docket Number	49409-0050 (315804)	

			OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS	-
	Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published		T²	
		68 9		
140	al		Glycoproteins Containing Certain Tumor-Associated and Blood Group Antigen Markers",	
~			Glycoconjugate Journal, 1989, Vol. 6, pp. 511-524.	
			VOET et al., Biochemistry, 1990, pp. 1096 and 1098	
		70°	VOET et al., Biochemistry, 1990, p. 78	
		71 9	VOLKMANN, M., et al., "Anti-p53 autoantibodies as serological marker in different tumor- entities", Clinical Chemistry, Volume 41, no. S6 part 2, 1995, pp. S221-S222	
			Abstract of VON MENSDORF-POUILLY et al.; Anticancer Research, Nov-Dec. 1997, Vol. 17, page 4184	
			VON MENSDORFF-POUILLY, S., "Humoral Immune Response to Polymorphic Epithelial Mucin (MUC-1) inpatients with Benign and Malignant Breast Tumours"; European Journal of Cancer, Vol. 32A, No. 8, pp. 1325-1331, 1996	
			WOLF, et al., "A Tumour-Associated Antigen from The Pleural Effusion of Patients with Squamous-Cell Carcinoma of Lung", Br. J. Cancer, 1978, Vol. 36, pp. 1046-1052.	
		75 •	Abstract of YAMAMOTO et al.; Proc. Amer. Soc. Cancer Res., March 1997, page 564	
		76 °	YAMAMOTO et al., "L-Myc Overexpression and Detection of Auto-Antibodies Against L-Myc in Both the Serum and Pleural Effusion from a Patient with Non-Small Cell Lung Cancer", Internal Medicine, 1997, Vol. 36, No. 10, pp. 724-727.	
		77 •	YAMAUCHI, et al., "Autoantibodies to C-MYC Nuclear Protein Products in Autoimmune Disease", 1989, pp. 117-119	
	_	78 °	ZISMAN et al.; Journal of Urology, 1995, Vol. 154, pp. 1052-1055	
	_	79°	Definition of "moncyte" in On-line Medical Dictionary downloaded on 2/5/05 from urlcancerweb.ncl.ac.uk	
	\top			
				ļ
				ļ

Examiner Signature	/Lynn Bristol/	Date Considered	03/27/2007

¹Unique citation designation number. ²Applicant is to place a check mark here if English language translation is attached.